

January 18, 2002

Mr. Daniel Troy  
Chief Counsel  
Food and Drug Administration  
Room 6-57 (GCF-1)  
5600 Fishers Lane  
Rockville, Maryland 20857-1706

Dear Mr. Troy:

The Generic Pharmaceutical Association (GPhA) submits the attached document which responds to your request for materials that will be used in a meeting scheduled for January 30, 2002 with various industry representatives. GPhA's members are looking forward to making progress on resolving serious problems with the regulatory and statutory framework which governs the review and approval of abbreviated new drug applications by the Food and Drug Administration (FDA). We believe that framework has become seriously flawed in its application of both legislative intent and the plain meaning of the statutory language. As a result, consumers are denied timely access to safe and effective generic medicines.

We wish to emphasize that it is our view the FDA cannot unilaterally resolve all of the problems which presently impede consumer access to generic medicines. Changes in technology and research methodologies, and a variety of legal strategies used by regulated companies since the enactment of the Hatch-Waxman Act have required FDA and the Courts to make piecemeal adjustments to the Act. Cumulatively, these changes have produced a nearly impossibly complex and contradictory review process that is unpredictable and subject to manipulation and abuse. The system begs for a more thorough reform than is possible through simply revising existing regulations and policies.

GPhA welcomes the dialogue you have invited our industry to participate in, and we strongly believe that some interim regulatory changes are needed and should be implemented. However, there is a real danger that the process of engaging in this dialogue could be used by some industry representatives as a justification to delay legislative reforms which otherwise would be considered and implemented by the U.S. Congress. FDA should exercise care that GPhA's discussions with you not have the appearance of, or become an actual impediment to, legislative reforms that are needed to address critical elements of the generic drug approval process. In particular, we are concerned that the discussions may be used by the brand industry who benefit from the

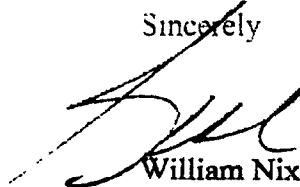
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present dysfunctional regulatory and statutory framework to argue that Congress should delay doing what needs to be done on the premise that any problems are being handled adequately at the administrative level.

To prevent our dialogue with you from being misinterpreted in this way, GPhA urges FDA to issue a statement that regulatory changes, while needed, cannot address basic problems inherent in the statutory scheme. FDA's statement should make clear that the dialogue you have initiated cannot be, and should not be viewed as, a substitute for needed legislative reform, or as a reason for Congress to defer consideration of proposed legislation to achieve that goal.

We look forward to discussing the regulatory improvements described in the attached submission.

Sincerely



William Nixon  
President and CEO

**Patent Submission Sample Format****DRAFT**

This is a format for submission of patent information for NDAs submitted under section 505 of the Federal Food Drug and Cosmetic Act. For more detailed information please refer to 21 CFR 314.53 for NDA # \_\_\_\_\_

Time sensitive patent information pursuant to 21 CFR 314.53 for NDA# \_\_\_\_\_

The following is provided in accordance with the Drug Price Competition and Patent Term Restoration Act of 1984:

Trade Name: \_\_\_\_\_  
Active Ingredient(s): \_\_\_\_\_  
Strengths: \_\_\_\_\_  
Dosage Form: \_\_\_\_\_  
Approval Date: \_\_\_\_\_

A. This information should be provided for each individual Patent submitted.

1. US patent number: \_\_\_\_\_
2. Identify each claim which covers the drug substance or the drug product for which the applicant submitted the application or which covers a method of using such drug substance or product and can reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale of the drug \_\_\_\_\_
3. Expiration date \_\_\_\_\_
4. Name of the Patent Owner: \_\_\_\_\_
5. US Agent (if patent owner or applicant does not reside or have place of business in the US) \_\_\_\_\_

B. For each claim identified in A2, please provide the following information:

1. The type of claim: \_\_\_\_\_
2. Drug Substance (Active Ingredient) \_\_\_\_\_ Yes \_\_\_\_\_ No
3. Drug Product (Composition/Formulation): \_\_\_\_\_ Yes \_\_\_\_\_ No
4. Method of Use: \_\_\_\_\_ Yes \_\_\_\_\_ No

C. For each Drug Substance claim identified, please provide the following information:

1. Does the claim cover the drug substance that is the subject of this application for which approval is sought in the same physical form as the drug substance for which approval is being sought? \_\_\_\_\_ YES \_\_\_\_\_ NO  
[If the answer is "NO," stop here; the patent may not be listed in the Orange Book.].

2. If YES, is the claim a product by process claim? \_\_\_\_\_ YES \_\_\_\_\_ NO

*[If the answer is "NO," please proceed to question 4.].*

3. If YES, has the product of the claim by the process for making it been known per se, independently, of that process and/or has the product, per se, been claimed in any other patent? \_\_\_\_\_ YES \_\_\_\_\_ NO

*[If the answer is "YES," stop here; the patent may not be listed in the Orange Book.].*

4. Statement of the basis for concluding why this claim meets 21 CFR 314.53

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D. For each Drug Product claim identified, please provide the following information:

1. Does the claim cover the approved formulation or composition and/or the formulation or composition for which approval is being sought?

\_\_\_\_\_ YES \_\_\_\_\_ NO

*[If the answer is "NO," stop here; the patent may not be listed in the Orange Book.].*

2. If YES, is the claim a product by process claim? \_\_\_\_\_ YES \_\_\_\_\_ NO

*[If the answer is "NO," please proceed to question 4.].*

3. If YES, has the product of the claim by the process for making it been known per se, independently, of that process and/or has the product, per se, been claimed in any other patent? \_\_\_\_\_ YES \_\_\_\_\_ NO

*[If the answer is "YES," stop here; the patent may not be listed in the Orange Book.].*

4. Statement of the basis for concluding why this claim meets 21 CFR 314.53

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E. For each Method of Use claim identified, please provide the following information:

1. Does the claim cover (a) an approved method of use of the approved drug product, or (b) a method of use of the approved drug product for which use approval is being sought, or (c) a method of use of the drug product for which use approval is being sought? \_\_\_\_\_ YES \_\_\_\_\_ NO

*[If the answer is "NO," stop here; the patent may not be listed in the Orange Book.].*

2. Statement of the basis for concluding why this claim meets 21 CFR 314.53

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The undersigned declares that all the above information have been provided in accordance with Title 28, Section 1746 entitled "Unsworn declarations under penalty of perjury".

Signed: \_\_\_\_\_

Date: \_\_\_\_\_

Title \_\_\_\_\_

Telephone Number \_\_\_\_\_